

Notice of Allowability

Application No.

10/780,640

Applicant(s)

AOKI ET AL.

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' amendment filed September 21, 2005.
2. ☒ The allowed claim(s) is/are 6 and 11.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 12-8-04, 2-15-05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Single
Paper

Raymond J. Henley III
Primary Examiner
Art Unit: 1614

EXAMINER'S COMMENTS/REASONS FOR ALLOWANCE

Comments

Applicants' amendment filed September 21, 2005 has been received and entered into the application. Accordingly, claims 1-5 and 10 have been canceled; claims 6 has been amended and claim 11 has been added. Accordingly, claims 6 and 11 all are of the claims in the application.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claim 6 is representative of the claims in the application and reads:

Claim 6 (Currently Amended): A method for treating hyperlipemia
hypertriglyceridemia in a patient in need of such treatment comprising administering an
effective amount of each a synergistically effective blood-triglyceride decreasing amount of a
combination of a pitavastatin and eicosapentaenoic acid or an ester thereof.

The closest prior art is Nakamura et al. (see IDS filed May 26, 2006, reference "AY"). Nakamura et al. teaches that HMG-CoA Reductase inhibitors, represented by pravastatin and simvastatin, combined with eicosapentaenoic acid ethyl ester ((EP-E"), resulted in a significantly decrease in serum triglyceride levels (see page 23, Tables 1 and 2). Nakamura et al. simply disclose the inclusion of an EPAE treatment with apparently a continuation of the two different statin treatments. There is, most notably, no comparison with a control which would be a

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continued statin treatment alone. Such would be necessary to determine whether or not one of ordinary skill in the art would have expected merely additive results or synergistic results. That is, a showing of a control group, a statin group, an EPA-E group and a combined statin-EPA-E group would be necessary to determine the quality of results that would have occurred.

In the present specification at Table 1, Applicants report a control group, a statin group, an EPA-E group and a combined statin-EPA-E. The difference in triglyceride (TG) levels between the control group and the pitavastatin group is that the pitavastatin group alone lowered (TG) levels by about 6 mg/dl. The difference in triglyceride (TG) levels between the control group and the EPA-E group is that the EPA-E group alone lowered (TG) levels by about 15 mg/dl. If additive results were present, one would have expect that when pitavastatin and EP-E were added, one would get at decrease in TG levels of 21 mg/dl. However, as shown in Applicants' data, which is statistically significant, the addition of pitavastatin and EP-E resulted in a TG value of 24 dl/mg. The result is greater than additive, i.e., synergistic, and is unexpected. Applicants' claims are directed to such unexpected results and thus are allowable.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).



Raymond J Henley III
Primary Examiner
Art Unit 1614

October 11, 2005